MATRIX Technology Accelerator Domain 1
Prevention Challenges: Overcoming Impediments to HIV Prevention
RFA2023-005

Fact-finding questions and responses

The MATRIX team thanks applicants who expressed interest in submitting a response to this Request for Application (RFA).

As a reminder, full applications are due by 8:00 AM Pacific time on August 1, 2023, and applicants should be from institutions in the United States, European Union, United Kingdom, Kenya, South Africa, and Zimbabwe. Each application should propose activities to address 1 of the 11 specified prevention challenges outlined in Table 3 of Section III of the RFA instructions, with successful applications focusing on and responding directly to the parameters of the prevention challenge, as outlined in Table 3. Furthermore, applications must involve significant participation and/or leadership from Kenyan, South Africa, and/or Zimbabwean investigators. We encourage applicants to carefully review what constitutes "nonresponsive areas of research" and Eligibility Information (as noted in Sections III and V of the RFA instructions, respectively) while developing their full applications to ensure alignment with RFA requirements and overall goals and objectives of the MATRIX project.

Please refer to the RFA for additional information or reach out to the PATH team at MatrixTechAcceleratorRFA@path.org.

Fact-finding questions from applicants and responses:

Best Practice Working Group (BPWG) 2

1. Could you kindly clarify if the focus of the working group is (a) sociobehavioral research (SBR) conducted during or in conjunction with preclinical and clinical studies and the integration of those findings into prevention product development decisions; or (b) findings from broader SBR on end user preferences and the translation of those findings into prevention product development decisions during preclinical and clinical studies?

   Both A and B would be applicable for this prevention challenge; an application integrating elements of both focus areas would be considered responsive and of interest.

2. Could you kindly confirm if the work could also include the review and development of culturally relevant SBR measures and terms to ensure greater ecological validity of measures and/or theoretical models used in clinical trials?

   Yes, an application proposing research to develop and test these approaches would be acceptable; however, please note that research activities would need to take place in either Kenya, South Africa, and/or Zimbabwe.

3. The RFA reads, “Best practices may also include the development of standardized SBR tools and data collection/analysis methods. Pilot experiments can be conducted to support proposed best practices when they include the use of specific data collection or analysis tools proposed as part of the best practice.” With the cost and duration limits in Table 2 of the RFA, could you kindly elaborate on the expected importance of inclusion of standardized tool or analysis development and/or a pilot study to the success of a proposal?

   While recognizing the time and financial limits to the scope of BPWGs, the expected importance of including standardized tool or analysis development and/or a pilot study would be dependent on the applicant’s proposed activities. Applicants who determine that pilot experiments are needed to provide insights to inform their best practices recommendations will need to adjust the size and scope of their proposed pilot studies to align with the cost and duration limits for BPWG applications, as specified in Table 2 of the RFA instructions.

   However, Section IX (Review Criteria) of the RFA instructions notes that “innovation is not a major driving factor for a proposed TT or BPWG project,” thus inclusion of a novel standardized tool or analysis development and/or a pilot study that would yield new data is optional.

Research Challenge 4

1. How limited am I to work on only samples from previous or ongoing clinical trials due to the possibility of lack of properly preserved samples or their unavailability?

   Applicants responding to this research challenge are not limited to biobanked samples from previous and ongoing trials, but may also collect vaginal secretions from healthy volunteers, as noted in the following excerpt from Table 3: “This [research challenge] may not conduct clinical studies but may collect vaginal secretions from healthy volunteers with or without pre-diagnosed bacterial vaginosis. If using biobanked samples from completed or ongoing trials, proposed activities should include development and implementation of quality control processes to ensure samples used are appropriate for the proposed analysis.”

2. Am I allowed to contextualize... HIV 1 materials... to mean anything either genomic material, proteins, lipids, carbohydrates, capsid etc. that is directly part of HIV 1 structure?

   If by HIV 1 materials, the applicant intends to identify a broad range of possible samples and/or matrices to be analyzed using specific matrices requiring techniques to analyze proinflammatory cytokines from clinical trials conducted in Kenya, South Africa, and Zimbabwe, the answer is yes. The application should use appropriate detection methodologies and sample matrices to perform the proposed research.

3. Does this study only limit me to cytokines or other immunological responses to the virus can be included?

Yes, an applicant assessing other immunological responses to the virus driven by proinflammatory cytokine findings would be responsive. Studies of other/associated immune responses should strengthen, inform, confirm, and/or justify the proinflammatory expression found within the female reproductive tract, in the context of the prevailing inflammatory state of the female reproductive tract. Studies of virus or natural immunological mechanisms and/or states that are either not related to or cannot be understood in the context of the female reproductive tract's inflammatory state would be non-responsive to the RFA.

General/cross-cutting

1. Could you kindly clarify if the total costs listed in Table 2 of the RFA instructions includes indirect costs?

Yes, Table 2 specifies the maximum budget amount/cost that can be requested, which is inclusive of all applicable direct and indirect costs.

2. Based on the budget template provided, can you kindly confirm organizations with multiple indirect rates should present one "effective rate" (or pooled rate) representing overall indirect rate needs on the project?

If the applicant has multiple indirect rates, the applicant's budget should only include one indirect rate that would be applicable to the applicant's proposed project/scope of work. If the indirect rate that the applicant uses in their budget is not a Negotiated Indirect Cost Rate Agreement (NICRA) with the US Government or represents a pooled rate, the applicant would need to share the cost methodology and audited financials to justify the indirect rate used in their submitted budget.

3. Am I allowed to include any other organization that I and my team may use in facilitating the study either midway or towards the end of the study for recognition during publishing?
Applicants should name all investigators and organizations who will be directly involved in leading or facilitating project activities as described in their application. Specifically, Section III of the technical application (Project Management and Roles of Project Team) should identify investigators or organizations with management and oversight responsibilities in the applicant's description of their proposed project management and oversight structure. This section should also describe the role and relevant expertise of all investigators and/or organizations involved in carrying out the applicant's proposed project.

All investigators and/or organizations do not need to be actively engaged from award start, but can be phased into project activities and engaged when needed to perform specific tasks or contribute to the proposed research, as dictated by the applicant's research plan.

Please refer to instructions detailed in Section III (Project Management and Roles of Project Team) of the Template for Technical Application and Section I (Personnel) of the Template for Budget Narrative for further guidance and application requirements.